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Guidance for the Reregistration of Pesticide Products Containing Fonofos (041701) as the Active Ingredient

(U.S.) Environmental Protection Agency
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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING
FONOFOS
(041701)

AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible unreasonable adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvemen Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements i I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This guidance document describes the Agency's regulatory position for all products containing the insecticide fonofos. The position is based on an evaluation of all the accepted uses of registered pesticide products under Section 3 and 24(c) of the FIFRA, with fonofos as the pesticide active ingredient. Other considerations include the known chemical and toxicological characteristics of the pesticide chemical and the established tolerances for residues in or on food commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants of fonofos products in order for their products to be registered under this document. Only those registration requirements for currently registered products containing fonofos are addressed here. Refer to the attached site/pest document for a listing of currently registered sites and pests. Future products that differ appreciably from those described in this guidance document may require that amendments be made to this document to reflect the differences.

B. Description of Chemical and Use Profile

Fonofos is a non-systemic organophosphorus insecticide (O-ethyl S-phenyl ethylphosphonodithioate) developed and initially marketed by Stauffer Chemical Company in 1967 under the trade name Dyfonate®. There is no American National

Standards Institute (ANSI) name for fonofos. However, fonofos is the official common name of the British Standards Institute (BSI), the International Standards Organization (ISO), and the Entomological Society of America (ESA). The current Chemical Abstract Service (CAS) registry number is 944-22-9. The Agency's Pesticide Chemical Code number is 041701.

Technical fonofos is a yellow liquid with a pungent mercaptan-like odor. The empirical formula is $C_{10}H_{15}OPS_2$. The molecular weight is 246.3. Other physical and chemical characteristics of fonofos include a boiling point of 212°F at 0.3 mm Hg, a melting point of $^{-}25$°F, a vapor pressure of 2.1×10^{-4} mm Hg at 25°C, a pH of 4-6, and a specific gravity of 1.154. Fonofos is almost insoluble in water (13 ppm at 20°C), but is miscible in common organic solvents (kerosene, xylene, MIBK, acetone and ethanol). Stauffer Chemical Company is the sole producer of fonofos in the United States.

There are 10 federally registered, sole-active-ingredient formulations of fonofos which include 2, 5, 10, 15 and 20% granular formulations and 1 lb and 4 lb/gallon emulsifiable concentrate formulations. There is one federally-registered, multiple-active-ingredient formulation containing 1 lb. emulsifiable concentrate of fonofos and 4 lbs. pebulate (Tillam®) and two 24(c) "Special Local Need" registrations which contain fonofos and thiram. In addition, there are 11 intrastate and 19 sole-active-ingredient 24(c) registrations. There are no products registered for manufacturing-use only.

Fonofos is used for the control of corn borers, garden symphylans, wireworms, and other soil insects. The major use (about 95%) is on corn; followed by peanuts and sugar beets (about 2% each), white (Irish) potatoes (about 1%), and less than 1% each on sugarcane and tobacco. Minor amounts are also used on some vegetable crops, lawns, and turf. There is a 2% granular formulation registered for home lawn and garden use; no usage data are available for this use.

Fonofos is primarily a soil-incorporated insecticide. Formulations are applied pre-plant, at-planting, and post-emergence to the soil using ground application equipment. Foliar applications to corn and sorghum may be applied using aerial equipment. The registered 2% granular formulation would be applied from a canister or by lawn fertilizer spreader. Emulsifiable concentrates of fonofos may be tank-mixed with certain herbicides and fluid fertilizers or water for use on some field and vegetable crops.

All of the emulsifiable concentrate formulations of fonofos, e,.g., 44% and greater, are restricted-use pesticides, and applicators must be certified or work under the direct supervision of applicators certified to apply these products (44 FR 45131, August 1, 1979).

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on fonofos, the Agency has made the following determinations:

1. Available data do not show that any of the criteria listed in Section 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of fonofos listed in this Guidance Document. However, gaps in the data base preclude the completion of the Agency's risk assessment.

2. Although the Agency is unable to complete a tolerance reassessment because of critical residue chemistry data gaps, the Agency concludes, based on available data, that no change in present tolerances, other than a pending tolerance petition for potatoes (see under TOLERANCE REASSESSMENT), is indicated at this time.

3. Fonofos is a highly toxic pesticide and uses may involve substantial human exposure to residues, but there is not sufficient data available to determine the extent of worker protection requirements such as reentry intervals. However, because of the Agency's concern about fonofos exposure, a 24 hour interim reentry interval has been established for all uses. Of particular concern are the hybrid seed corn use, exposure when soils are wet, and use in high exposure situations such as suckering of tobacco. Also of concern is exposure to persons, especially children, and pets from the 2% granular used for home lawns and

vegetable gardens.

4. Residues of fonofos and its oxon have been found to accumulate in carrots. Therefore, carrots should not be included in any crop rotation system where fonofos is applied.

5. The restricted use classification for all emulsifiable concentrate formulations containing fonofos at 44% and greater, will continue. In addition, the Agency has determined that the 20% granular formulation should be classified as a restricted use product.

6. Manufacturing-use and end-use products containing fonofos may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Guidance Document.

7. Registrants must provide, or agree to develop, additional data as specified in the tables, in order to maintain existing registrations or to permit new fonofos registrations.

D. REGULATORY RATIONALE

The Agency has determined that it will continue to allow the registration of fonofos after considering the following:

1. Under FIFRA, the Agency cannot cancel or withhold registration simply because the data are missing or are inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, the issuance of this Guidance Document provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that

time whether they will affect the registrations of fonofos.

2. Data available are insufficient to fully assess the toxicological properties of fonofos. Subchronic 90 day rat and dog feeding studies are necessary to fulfill the data requirements for fonofos. However, a review of the 90 day dog study showed it to be supplementary, but an adequate 2 year dog study on file permits fulfillment of the requirement for the non-rodent study. Therefore, only a 90 day subchronic rat study is required. There are several major data gaps which are essential for determining the extent of the human hazard. Studies must be submitted on neurotoxicity, subchronic toxicity, chronic feeding toxicity, teratogenicity, oncogenicity, and mutagenicity.

3. Available data are insufficient to fully assess the environmental fate of fonofos. Data gaps exist in all categories except aerobic soil metabolism. The preliminary laboratory mobility study suggests that fonofos may be relatively immobile in sandy loam and silt loam soils, and mobile in quartz sand. It was not appreciably mobile in runoff water from a loam soil, nor does it volatilize from soil, but it is fairly volatile in water. It degrades in aerobic soils with a half-life of approximately 3-16 weeks. In the field, fonofos dissipates with a half-life of approximately 4-7 weeks. Data indicate that fonofos is only moderately persistent. Fonofos has been found in tailwater pit sediment and water samples at <770 and <6 ppb, respectively. Fonofos is accumulated in bluegill sunfish and has a bioconcentration factor of 150X in bluegill edible tissue, but 80% of the accumulated ^{14}C residues

are depurated within 3 days. Preliminary laboratory leaching/ mobility and disappearance data indicate that fonofos may have the potential for moving into ground water through sand soil types. This preliminary assessment was based on a laboratory soil column test that was determined to be deficient. A repeat of this test is therefore required. Preliminary data from leaching/mobility and disappearance studies are insufficient to impose a label restriction for fonofos at this time. (see Table A page 45, footnote 9). The Agency has requested additional data on leaching/mobility of fonofos, and following review of the requested data, the Agency may impose label restrictions to prevent possible ground water contamination.

4. Based on studies available to assess the hazard to wildlife and aquatic organisms, fonofos is characterized as moderately to highly toxic to birds and highly toxic to freshwater fish and saltwater organisms. Simulated avian field studies indicate that granular treatments of fonofos may result in some mortality as well as brain AChE inhibition but that effects are not considered likely to diminish wildlife resources. Further

aquatic risk analysis is contingent upon submission of pertinent environmental fate studies and data gap studies listed in the Table for Ecological Effects. With respect to potential hazards to federally endangered/ threatened species, fonofos is currently being reviewed by the Agency and The Office of Endangered Species (OES).

5. Reported pesticide incidents cited in the Pesticide Incident Monitoring System (PIMS) through August 1977 include 21 incidents involving human injury. There were two reported fatalities. In addition, numerous reports of cattle, dog, raccoon, and fish deaths have been reported. These incidents were largely the result of accidents and careless use of fonofos and/or used containers that once contained fonofos.

6. No Federal reentry interval has existed prior to the issuance of this guidance document for workers entering fields treated with fonofos. Because fonofos is highly toxic and uses of fonofos may involve substantial exposure to residues, the Agency is requiring a 24 hour interim reentry interval for all uses of fonofos. Several uses and use conditions are of particular concern to the Agency. These include worker exposure from the use of fonofos on hybrid seed corn and worker exposure

from treated soil that is wet. The State of California is reporting worker exposure problems with soil incorporated pesticides similar to fonofos. California also requires at least a 24 hour interval for toxicity category I pesticides.

The Agency is also concerned about fonofos used on other crops where work tasks involve prolonged, intimate contact with plant surfaces. Among these tasks are the topping and suckering of tobacco. Another area of concern is exposure to individuals, especially children, and pets from the home lawn and vegetable garden uses of the 2% product. Although the 2% granular formulation has a lower concentration of active ingredient than the other granular formulations, the per unit application rate for the active ingredient is equivalent to the per unit rate of application for the 5, 10, 15, and 20% formulations. Therefore, the Agency believes it is appropriate to impose an interim 24 hour reentry interval until data are submitted to enable the Agency to evaluate the hazards of the homowner uses.

7. Preliminary data from rotation crop studies indicates that carrots accumulate fonofos residues of approximately 0.4 to 1.31 ppm. The group tolerance for root and tuber crops is 0.1 ppm for fonofos plus its oxon. Preliminary information also indicates that carrots generally absorb more insecticide than any other crop For this reason, a carrot crop rotation restriction is required.

8. Classification of Fonofos. The Agency has determined that certain formulations of fonofos warrant classification as restricted use pesticides. These include all emulsifiable concentrates 44% or greater and the 20% granular formulation. The

restriction being imposed is limitation of use to certified applicators or persons under their direct supervision. Granular formulations of 2%, 5%, 10% and 15% are not classified for restricted use.

The criterion used for restricting the emulsifiable concentrates 44% and greater is the acute dermal toxicity of the formulations. These formulations were restricted by regulation on August 1, 1979 (44 FR 45132). The criterion used for restricting the 20% granular formulation is the acute oral toxicity of the formulation. The 20% granular formulation was proposed for restricted use on August 1, 1979 (44 FR 45219). The Agency never promulgated a final rule classifying the 20% granular formulation for restricted use. The principal reasons for the delay in promulgation has been the the concerns raised by several registrants and the Scientific Advisory Panel over the avian effects triggger and the concerns raised by Stauffer Chemical Co. over the use of the acute oral trigger as a criterion for restricted use classification. The Agency has decided that the avian effects trigger should not, at this time, be used as a basis for restricting fonofos granular formulations pending further development of Agency efforts to develop data and protocols for assessing avian hazards. However, granular formulations of other active ingredients that were proposed for restricted use in the same rule as fonofos granulars and which have been demonstrated to be more hazardous than fonofos to avian species may be classified for restricted use on the basis of adverse avian effects.

The Agency has also recently decided to cease using the classification by regulation process as a routine mechanism for classifying uses/formulations for restricted use. Classification by regulation was developed as an optional procedure to classifying through reregistration. An alternative mechanism was needed because the programs to train and certify applicators was being implemented beginning in 1975 and procedures for reregistration had not been instituted at that time. The appropriate time to consider classification decisions, however, is during the development of the Registration Standard, which the Agency is now able to do because the standard development process is fully operational. Classifying through the standard will enable the Agency to thoroughly evaluate the risks and benefits of a restricted use classification and will be a more efficient use of Agency resources.

The details on labeling requirements for the 20% granular product, such as release for shipment dates, labeling of products at the distributor and retail level and requirements for submitting restricted use labeling to to the Agency for approval, have not been finalized by the Agency. However, the Agency has determined that the restricted use labeling for the 20% granular formulation is to be implemented in time for the 1986 growing season. Labeling for the emulsifiable concentrates previously restricted is to remain in place. Classification decisions on the granular formulations of the other active ingredients that were proposed for restricted use at the same time as the fonofos 20% granulars (see 44 FR 45219) will also be made as standards for these chemicals are developed or by amending existing standards. However, the 1986 growing season restricted use effective date will apply to any granular formulations of 6 active ingredients that were proposed for restricted use at the same time as fonofos granulars, if it is determined that these formulations still warrant restriction. These 6 active ingredients are: carbofuran, disulfoton, ethoprop, fensulfothion, phorate and terbufos. Registrants of these active ingredients and fonofos will be notified of compliance requirements by certified mail.

Active ingredients that have been evaluated through the classification by regulation process tracked the procedures in §162.11(c). Briefly that section requires that the existing toxicity categories be used to identify "candidates" for restricted use. The principal human effects triggers for chemicals used in non-domestic settings are the Toxicity Category I criteria, i.e., acute dermal LD50 200mg/kg; acute inhalation LC50 - 0.2mg/l; acute oral LD50 50 mg/kg. Following the identification of candidates based on these criteria, §162.11 calls for an evaluation of label adequacy. If certain subjective criteria are met that indicate current label language or new label language could be developed to prevent unreasonable adverse effects, then the formulation/use in question can remain general. Section 162.11 also requires an evaluation of other information such as accident history, epidemiology studies, etc. to determine if a formulation/use should be restricted. The Agency determined that the 20% granular formulation failed to meet the label adequacy test for general use as described in §162.11(c)(3). Specifically, the Agency determined that:

1) failure to follow directions for use and/or proper disposal may result in serious adverse effects to individuals through accidental ingestion, breathing dust from open bags, or by failure to wear rubber gloves and/or undergo proper washing [162.11(c)(3)(ii)].

2) failure to follow directions to not store in and around the home or garden may result in adverse effects for individuals contacting treated surfaces or eating treated vegetables [162.11(c)(3)(ii)].

3) following common use practices in loading or cleaning equipment could result in serious adverse effects to the applicator [162.11(c)(3)(iii)].

As noted earlier in this section, the registrant of fonofos, Stauffer Chemical Co. expressed concern over the use of acute oral toxicity data as a basis for restricting granular formulations. The Agency's rationale for relying on acute oral data is presented in the preamble to the proposed rule classifying fonofos for restricted use. Specifically, the Agency was concerned with the potential for inadvertent ingestion of granulars by users during loading, application, equipment calibration, equipment maintenance and cleaning, and handling of containers during disposal. The Agency was also concerned with the possible accidental ingestion of granulars by children, pets and farm animals during the storage of granular formulations. The criteria followed by the Agency in making classification decisions (§162.11(c)) provide for an extra margin of safety in domestic use situations where children and pets are likely to have access to pesticides. In general the farm environment is considered to be non-domestic, but children living on the farm, pets, and farm animals often have access to stored pesticides and the Agency believes that this fact should be considered in assessing the hazard of non-domestic use pesticides. There has been one reported case of ingestion of fonofos 20% granulars by two children, one of whom died. In addition, several cases of farm animals dying from ingesting stored granular pesticides, including fonofos, have been reported.

Prior to the Agency proposing fonofos 20% granulars for restricted use by regulation, it sought advice from USDA Cooperative Extension Service personnel and State regulatory officials in States where granular formulations are widely used. They confirmed that oral toxicity of granular formulations was a legitimate concern in non-domectic use situations. Specifically, they mentioned the importance of oral toxicity with respect to potential hazards associated with equipment cleaning, maintenance and product storage.

During the public comment period for the proposed regulation, (August - October 1979), Stauffer Chemical Co. submitted comments on several aspects of the proposed classification of fonofos 20% granulars for restricted use. Of most concern was the use of acute oral toxicity data as a basis for restriction. A discussion of Stauffer's comments follow.

Stauffer stated that the use of acute oral mammalian toxicity as a trigger for restricted use of fonofos granular products is inappropriate. Stauffer noted that FIFRA "... recognizes the general inappropriateness of the acute oral trigger in section 3(d)(1)(C)(i) by limiting the requirement of application only by certified applicators to those cases involving a hazard from acute dermal or inhalation toxicity. It specifically excludes use of acute oral toxicity for classification purposes." The Agency does not interpret 3(d)(1)(C)(i) as a prohibition against the consideration of oral toxicity in classifying pesticides, but rather a requirement that if a use/formulation is classified restricted solely on the basis of acute dermal and/or inhalation hazard, limiting its use to certified applicators or individuals under their supervision is the only restriction authorized by section 3(d)(1)(C).

Further, Stauffer stated that the Agency "recognized the general inappropriateness of using acute oral toxicity" in the preamble to section 3 regulations, July 3, 1975, (40 FR 28257). In this portion of the preamble, the Agency states that "if a formulation intended for non-domestic use falls into toxicity category I based on dermal, inhalation, skin or eye effects such formulation will be considered a candidate for restricted use." The absence of reference to oral toxicity in the preamble, while somewhat at odds with 40 CFR 162.11(c)(2), Classification of Previously Registered Products, does not prohibit or limit the use of oral toxicity as a criterion for identifying formulations/uses as candidates for restricted use. FIFRA clearly gives the Administrator authority to consider other relevant information in deciding which formulations/uses should be restricted under section 3(d)(1)(C)(ii). Further, §162.11(c)(2) states "... the existing Toxicity Category determinations shall be used to establish whether the pesticide use(s) is a candidate for general or restricted use classification." The acute oral toxicity as well as acute dermal, inhalation and skin and eye effects are used to determine the toxicity category of a formulation.

Stauffer suggests that the Agency's definition of "use" [40 CFR 162.3(oo)] places storage concerns outside the requirements of certification. The Agency's position has been that certain aspects of storage, but not all, are outside the scope of the restricted-use program insofar as certification is involved. For instance, it seems unreasonable to require those individuals in the distribution chain from producer to retailer to be ceritifed, since such individuals do not, except in unusual circumstances, come in contact with the actual pesticide; further, the storage of such pesticides in a retail establishment or warehouse would not pose any significant risk to children or farm animals. However, once a pesticide product is in the hands of the actual user there are significant risks associated with the subsequent storage of pesticides, and in this context storage is an appropriate concern for the applicator certification program. In this regard, acute oral toxicity of a formulation is a relevant factor that should be considered in any classification determination.

Stauffer also noted that: (1) Proper use of granular Dyfonate (fonofos) eliminates the potential for any oral ingestion exposure because application of the granules leaves them widely dispersed or actually incorporated in soil, and therefore the granules are not readily available for human, pet or livestock ingestion after use. (2) By following clear label instructions to wear gloves and to wash hands, arms, and face before eating or smoking, the applicator will avoid any oral exposure during preparation for and application of Dyfonate (fonofos) granular products. Stauffer also noted that this fact was specifically recognized in the EPA/State meeting held to discuss Dyfonate (fonofos) granulars where the acute hazard was characterized as low. (3) Label instructions also instruct the user not to store Dyfonate (fonofos) in or around the home or with food or feed.

In response, the Agency notes that one of the basic assertions made by Congress in passing the 1972 FIFRA amendments was that label requirements by themselves had not been adequate to protect the pesticide user or other persons form the adverse effects of exposure to pesticides. The whole concept of classififcation and the limitation classification places on restricted use products, i.e., use by certified applicators, individuals under the supervision of a certified applicator or other regulatory restrictions that may be imposed by the Administrator, rests on the recognized inadequacy in certain cases of labels and labeling alone to provide adequate protection for man and the environment.

The Agency has translated this intent into operational guidelines for classification. The manner in which the Agency measures potential hazard is to examine both the inherent toxicity of a pesticide formulation and the likelihood of exposure during use. With respect to acute oral toxicity, the Agency uses toxicity category I, an acute oral LD50 value of 50 mg/kg or less, as a criterion for identifying candidate formulations for restricted use. Although this is necessarily an "arbitrary" value, in the sense that some other threshold could have been used instead, it is one that has been in use for many years, is the key to EPA's precautionary labeling requirements, and is generally acceptable and recognized as a benchmark by registrants, users, etc.

Regarding the question of exposure; the Agency believes there is a potential for inadvertent ingestion during storage and loading, etc., that supports restriction. Although the attendees of the EPA/State meeting referred to by Stauffer did conclude that the hazard to the applicator from Dyfonate (fonofos) was low, the State participants, regulatory and Extension personnel from States where granulars are widely used, did express overall concern that granulars with an oral LD50 equal to 50 mg/kg or less, toxicity category I, should be classified for restricted use. This would include Dyfonate (fonofos) 20% granular formulations.

Stauffer also claimed that Dyfonate(fonofos) granular products do not exceed the acute oral toxicity trigger for category I. The registrant suggests that the rabbit is a more appropriate test species than the rat, the test species for which the Agency has data, because of the difficulties in administering granulars to rats imposed by their size and because the rabbit is an equally sensitive species. Further, Stauffer states that the extrapolated

LD50 for all Dyfonate (fonofos) granular formulations is above 50 mg/kg in either the rat or rabbit.

Regarding Stauffer's contention that the rabbit is a more appropriate test species than the rat, the Agency notes that the difficulties cited by the registrant is administering granules to rats are not apparent from the acute oral toxicity studies using various vehicles to administer the granular formulations of Dyfonate(fonofos) 20% granulars. These data show that the LD50 values of the 20% granular administered to female rats via a capsule, the method purported to traumatize the rat, are identical to the LD50 value for female rats administered powdered granules suspended in corn oil. A similar relationship in LD50 values is also observed in tests conducted with male and female rabbits using capsules and a corn-oil medium although the LD50 value for the male and female rabbit is greater that 50 mg/kg.

The data on hand also show clearly that the female rat is consistently the most sensitive indicator of the acute oral toxicity of fonofos, with LD values less than 50 mg/kg for the 20% formulation. Further, the rat is the preferred species for acute oral toxicity testing (see the proposed Registration Guidelines, 43 FR 37355, August 22, 1978). The rat historically has been used for this type of testing and the Agency's acute oral data base is built on rat data. The introduction of data on another species would unnecessarily complicate toxicity comparisons between products.

The registrant's claims concerning the fact that the extrapolated data from the technical material show that the acute oral LD50 for both rats and rabbits is greater that 50 mg/kg is not persuasive since data are available on the formulated product. Although the Agency sometimes extrapolates from technical material, these extrapolated values would not be considered to be more valid than the actual data on the formulated product which the Agency used in its evaluation.

Finally, in this area the Agency has long been guided by principles enunciated by the National Academy of Science which has stated that, "While extrapolation of test results to humans may not always be valid, the correlation is reasonably good for single oral doses. Materials highly toxic to rodents generally are highly toxic to humans. Marked variation in responses of different species calls for the assumption that man is at least as sensitive as the most sensitive species studies." Emphasis added. National Academy of Science Publication 1138, Revised, 1977).

Following the submission of comments during the public comment period, Stauffer began developing an alternative approach to the evaluation of hazards of granular pesticides. Stauffer suggested a "modeling" approach to hazard assessment which appears to provide improved methods for estimating exposure from inhalation of granular fines (small particles) and the resulting biological responses to inspiration of small fines. Although the Agency believes this approach may ultimately be valuable in determining hazards for applicators it does not address the Agency's principal concern over potential inadvertent ingestion by children, pets and farm animals.

Stauffer has also redesigned their 20% granular product label with new graphics, coloring and more prominent warnings about the potential hazard to livestock from contaminated feed. The Agency believes that these changes make for an improved product label, but will not reduce the risk to such a degree that a restricted use classification is no longer needed.

Following submission and evaluation of data required by the standard, e.g. chronic data, it may be necessary to classify additional formulations of fonofos for restricted use.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

This Guidance Document covers products that contain fonofos as a pesticide active ingredient, and the chart in the Introduction describes the extent to which such products are subject to this Document. Applicants for registration of such products must comply with all terms and conditions described herein. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for reregistration must follow the instructions contained in the Guidance Document and complete and submit the appropriate forms within the specified times. End-use products must be in compliance with the label changes specified in this Document

F. ACCEPTABLE RANGES AND LIMITS

1. To be fully covered by this Guidance Document, manufacturing-use products and end-use products must contain fonofos as the sole active ingredient. Each product proposed for registration must be fully described with appropriate certification of limits.

2. The Agency will consider for registration any product whose acute toxicity category (I,II,III, or IV) is supported by adequate acute toxicity data and labeling, including appropriate precautionary statements.

G. REQUIRED LABELING

All manufacturing-use products and end-use products containing fonofos must bear appropriate labeling as specified in 40 CFR 162.10. Amended labeling incorporating all label changes specified in this Guidance Document must be submitted to the Agency within 90 days of receipt of this Guidance Document.

1. Label Requirements for Manufacturing-Use Products

a. Ingredient Statements

The ingredient statement for MP's must list the active ingredient as:

fonofos: O-ethyl S-phenyl ethylphosphonodithioate

b. Use Pattern Statement

All MP's must state on the product label that they are intended only for formulation into end-use products for any of the use patterns listed below. A limiting factor will be the data that support these use patterns. No use may be included on the labeling where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

- Terrestrial, non-domestic, food uses on: asparagus, beans (dry, lima and green), beets, broccoli, brussels sprouts, cabbage, cauliflower, cole crops (seed only), corn (field, sweet and pop), mint (peppermint and spearmint), onion (bulb), peanuts, peppers, potatoes (Irish and sweet), radishes, sorghum (grain), strawberries, sugarbeets, sugarcane and tomatoes.

- Terrestrial, non-domestic, non-food use on: ornamental turf (bluegrass, bahiagrass, Bermudagrass, St. Augustinegrass and zoysiagrass) and tobacco.

- Domestic outdoor use on: lawns, beans (snap), beans (lima), beets, broccoli, brussels sprouts, cabbage, cauliflower, corn, potatoes (white), potatoes (sweet), radishes, tomatoes, and strawberries.

c. Precautionary Statements

Labels for all MP products containing fonofos must bear statements reflecting the hazards to humans based on toxicity, environmental hazards, and physical/chemical hazards of the compound.

- Statement of Environmental Hazard

  The statements below are required to appear on MP products containing fonofos:

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance contact your regional office of the EPA.

2. Label Requirements for End-Use Products

a. Ingredients Statement

The ingredient statement for end-use products must list the active ingredient as:

fonofos: O-ethyl S-phenyl ethylphosphonodithioate

b. Use Pattern Statements

The following statements, in addition to current label requirements, are required to appear on all end-use products except the 2% granular product:

> "Do not enter treated areas for 24 hours after application."
>
> "Wear gloves and shoes when handling or applying."

The following statements, in addition to current label requirements, are required to appear on the 2% granular product for home lawn and vegetable use:

> "Lawns - Water material into soil immediately after application. Do not enter treated areas or allow children and pets on lawns for 24 hours and until grass has completely dried."
>
> "Vegetable Gardens - Do not enter treated areas for 24 hours after application."
>
> "Wear gloves and shoes when handling or applying."

The following statement is required to appear on all end-use products with directions for use on food crops:

> "Do not rotate with carrots."

c. Precautionary Statements

Labels for all end-use products containing fonofos must bear statements reflecting the hazard to humans based on toxicity, environmental hazards and chemical/ physical hazards.

- Statement of Human Hazard.

  Fonofos is registered in toxicity categories I,II, and III. The required precautionary language is found in 40 CFR 162.10.

- Statement of Environmental Hazard.

  The following statements are required to appear on all end-use products containing fonofos:

ENVIRONMENTAL HAZARDS

> This pesticide is toxic to fish and wildlife. Birds feeding in treated areas may be killed. Remove or cover granules if spills occur. Runoff from treated areas may be hazardous to fish in neighboring areas. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of waste. For guidance contact your regional office of the EPA.

H. TOLERANCE REASSESSMENT

Tolerances are established for residues of the insecticide O-ethyl S-phenyl ethylphosphonodithioate, including its oxygen analog O-ethyl S-phenyl ethylphosphonothioate*, in or on raw agricultural commodities as follows (40 CFR 180.221):

0.5 part per million in or on asparagus.

0.1 part per million (negligible residue) in or on bean forage, bean vine hay, fresh corn including sweet corn (kernels plus cob with husk removed), corn grain (including popcorn), corn forage or fodder (including sweet corn, field corn, and popcorn), fruiting vegetables, leafy vegetables, mint (peppermint, spearmint, peppermint hay, and spearmint hay), pea forage, pea vine hay, peanuts, peanut forage, peanut hay, peanut hulls, root crop vegetables, seed and pod vegetables, sorghum (grain, fodder, and forage), soybean forage, soybean hay, strawberries, sugar beet tops, and sugarcane.

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* The 1983 CFR citation reads S-ethyl S-phenyl ethylphosphonothiolate and should be corrected.

Canada has established tolerances for residues in corn, onions, potatoes and sugar beets. These tolerances are at the same level as the U.S. tolerances for these crops. A pending petition in the Agency to increase the tolerance for residues in potatoes (if established at 0.5 ppm) will result incompatibility between the U.S. and Canadian tolerances. There is no listing for this pesticide by Mexico or the Codex Alimentarius.

The nature of the residue of fonofos in plants is adequately understood, but there are no data on food-animal metabolites. Poultry and ruminant metabolism studies, in addition to a poultry feeding study and a ruminant feeding study, are required. There are no tolerances for meat, milk, poultry, eggs and processed commodities. However, there is a possibility of carry-over of residues from treated crop plants fed to animals. If residues occur, additional tolerances and approved analytical methods will be required.

The existing residue data are inadequate to support reassessment of present tolerances for the major uses on corn, peanuts, sugarbeets, potatoes (Irish), sugarcane, and tobacco, nor for several minor crops. No new crop groupings (48 FR 29855, June 29, 1983) can be established for the categories Root and Tuber Vegetables; Leaves of Root and Tuber Vegetables; Bulb Vegetables; Legume Vegetables (Succulent or Dried); Foliage of Legume Vegetables; Fruiting Vegetables (Except Curcurbits); Small Fruits and Berries; Cereal Grains; and Forage, Fodder, and Straw of Cereal Grains. However, the new crop grouping, Brassica (Cole) Leafy Vegetables, can be established at this time.

No change in the tolerance expression for fonofos and its oxygen analog (oxon) are required at this time. A tolerance reassessment may become neccessary once data gaps are filled.

Based on the presently established tolerances, the Theoretical Maximum Residue Concentration (TMRC) from residues of fonofos and its oxon in the human diet is calculated to be 0.0418 mg/day from a 1.5 kg food diet for a 60 kg person. The Acceptable Daily Intake (ADI) for fonofos and its oxon is 0.002 mg/kg/day. This is based on a two-year dog feeding study with a No Observable Effect Level (NOEL) of 8 ppm and a safety factor of 100. The Maximum Permissible Intake (MPI) is 0.120 mg/day/60 kg individual. Thus, the percentage of the

ADI utilized by the established tolerance is 34.84%. This would be increased to 41.63% under a 0.2 ppm potato tolerance, and 61.98% if a 0.5 ppm potato tolerance is established.

Corrections to 40 CFR 180.221 will be taken as follows:

- The tolerances under the old crop group "Root Crop Vegetables" will be converted to individual tolerances: Beets, Table; Onions; Potatoes; Radishes; Sugar Beets; Sweet Potatoes; and Turnips.
- The tolerances under the old crop group "Leafy Vegetables" will be converted to individual tolerances: Beets, Table (leaves); Radishes (Tops); and Sugar Beet Tops.
- The tolerances under the old crop group "Seed and Pod Vegetables" will be converted to individual tolerances: Beans; Peas; and Soybeans.
- The tolerances under the old crop group "Fruiting Vegetables" will be converted to individual tolerances: Peppers; and Tomatoes.
- A new group tolerance for "Brassica (Cole) Leafy Vegetables" will be established.
- The individual tolerances previously established will be maintained.
- The chemical designation for the oxygen analog of fonofos will be corrected to read:

  O-ethyl S-phenyl ethylphosphonothioate

Index of Currently Acceptable Uses
EPA Index to Pesticide Chemicals

1701

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE*

TYPE PESTICIDE: Insecticide

FORMULATIONS: G (2%, 5%, 10%, 15%, 20%); EC (1 lb/gal, 4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS:
Definition of Terms:
Claims for pest control limited to suppression of population are indicated by parenthesized pest name.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

AGRICULTURAL CROPS

General Warnings and Limitations: Do not enter treated areas for 24 hours after application. For home vegetable uses (2 percent granular formulation) wear gloves and shoes when handling or applying and water material into soil immediately after application. Do not rotate with carrots. For preplant broadcast soil application, incorporate into the top 2 to 3 inches of soil unless otherwise specified. For emulsifiable concentrate formulations, apply in 20 to 50 gallons of water per acre by tractor mounted spray equipment or larger custom applicator type vehicles. Remove or cover granulues if spills occur.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
6002AA	Asparagus		0.5 ppm 30 day preharvest interval through 10 pounds per acre for broadcast soil application.
DAABA	Garden symphylan	3-10 lb/A (5-10% G)	Use limited to CA. Broadcast soil application. Incorporate into the soil with cultivator.

*fonophos

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/15001AA /15003AA	Beans, Dry Beans, Green		0.1 ppm (bean forage, bean vine hay) 0.1 ppm (seed and pod vegetables) Broadcast soil application (preplant) through 4 pounds per acre. Emulsifiable concentrate formulation may be tank mixed with S-ethyl dipropylthiocarbamate in fluid fertilizer or water. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
INAVAAA	Wireworms	4 lb/A (10% G) (4 lb/gal EC)	
IOACAHA	Seedcorn maggot	2-4 lb/A (10% G) (4 lb/gal EC)	Use limited to Northwestern states. Preplant broadcast soil application. Incorporate into the top 2 to 4 inches of soil. Apply the higher rate where population pressure is severe.
		4 lb/A (4 lb/gal EC)	Use limited to Northeastern states. Preplant broadcast soil application. Incorporate into the top 2 to 4 inches of soil.
IJDAABA	Garden symphylan	0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
INAVAAA	Wireworms	0.16 oz/ 100 sq.ft (2% G)	

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/15025AA	**Beans, Lima**		0.1 ppm (bean forage, bean vine hay) 0.1 ppm (seed and pod vegetables) Broadcast soil application (preplant) through 4 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
INAVAAA	Wireworms	4 lb/A (4 lb/gal EC)	Use limited to CA. Preplant broadcast soil application. Incorporate into the soil by discing.
/28002AA	**Beets**		0.1 ppm (root crop vegetables, leafy vegetables) Broadcast soil application (preplant) through 2 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IOACADA IJDAABA	Cabbage maggot Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13005AA /13006AA /13007AA /13008AA	Broccoli Brussels Sprouts Cabbage Cauliflower		0.1 ppm (leafy vegetables) Broadcast soil application (preplant or at time of planting) through 4 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) and 20 percent granular formulations are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Broadcast soil application prior to or at time of seeding or transplanting. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at time of seeding or transplanting. Incorporate with a rake or power tiller.
IOACADA	Cabbage maggot	4 lb/A (15-20% G)	Broadcast soil application prior to or at time of seeding or transplanting. Incorporate into the soil by discing. Not recommended in the Northwestern United States.
		1-2 lb/A [200-400 gal/A] (4 lb/gal EC)	Use limited to Northeastern states. Soil drench to transplants immediately after transplanting. Apply by ground equipment with drop nozzles to direct spray to base of plants.
/13004BA	Cole Crops (seed crop)		0.1 ppm (leafy vegetables)
IOACADA	Cabbage maggot	2 lb/A (5% G)	Broadcast soil application to seed crop prior to or at time of seeding or transplanting. Incorporate into the soil by discing.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28006AA /15004AA /15005AA	Corn, Field Corn, Pop Corn, Sweet		0.1 ppm fresh corn including sweet corn (kernels plus cob with husks removed), corn grain (including popcorn), corn forage or fodder (including sweet corn, field corn, and popcorn) 45 day preharvest and 30 day pregrazing interval through 1 pound per acre for foliar application and postemergent soil application at cultivation (band). Broadcast soil application (preplant) through 4 pounds per acre. Banded soil application (at planting) through 2 pounds per acre. Unless otherwise specified, row application per acre rates are based on 38 to 40 inch row spacing. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) and 20 percent granular formulations are RESTRICTED USE PESTICIDES.
ITBCALA INAVAAA	(Black cutworm) (Wireworms)	1 lb/A or 1.2 oz/ 1,000 ft row (10-20% G)	Soil application at planting (band). Apply a 6 to 8 inch band. Incorporate into the top 0.5 to 1 inch of soil either by applying ahead of press wheels or by dragging a short length of chain behind the press wheels. Do not place in direct contact with the seed.
ITBMBOA	Lesser cornstalk borer	2 lb/A or 2.4 oz/ 1,000 ft row (10-20% G)	
INAMBLA	Northern corn rootworm	0.75-1 lb/A or 0.9-1.2 oz/ 1,000 ft row (10-20% G) or 0.75-1 lb/A (5% G) (4 lb/gal EC)	
INAMBMA	Southern corn rootworm		
INAMBOA	Western corn rootworm		
IOACAHA	Seedcorn maggot	0.75-1 lb/A or 0.9-1.2 oz/ 1,000 ft row (10-20% G)	

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Corn, Field cluster (continued)		
INAKABA	Seedcorn beetle	0.75-1 lb/A or 0.9-1.2 oz/ 1,000 ft row (10-20% G)	Use limited to Central and Midwestern corn growing areas. Soil application at planting (band). Apply a 6 to 8 inch band. Incorporate into the top 0.5 to 1 inch of soil either by applying ahead of press wheels or by dragging a short length of chain begind the press wheels. Do not place in direct contact with the seed.
ITBMCCA	European corn borer	1 lb/A [minimum 30 inch row spacing] (10-20% G)	Foliar application. Band or broadcast over the corn so the granules fall into the whorl. Broadcast application may be applied by aircraft. Apply 6 to 8 inch bands over corn rows by ground equipment. For European corn borer, apply when 50 percent of the plants show first generation borer feeding. For second generation, apply when counts show 100 egg masses per 100 plants. For southwestern corn borer, apply when newly hatched larvae first appear and repeat as needed to control later generations.
ITBMAYA	Southwestern corn borer		
IJDAABA	Garden symphylan	0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
INAVAAA	Wireworms	0.16 oz/ 100 sq.ft (2% G)	
INAMBLA	Northern corn rootworm	0.75-1 lb/A or 0.9-1.2 oz/ 1,000 ft row (10-20% G)	Postemergent soil application at cultivation (band). Apply a 6 to 8 inch band over the corn rows. Cover treated band with 2 to 3 inches of soil by making application ahead of disc hillers or cultivation equipment. Apply in May or June at first sign of larval activity.
INAMBMA	Southern corn rootworm		
INAMBOA	Western corn rootworm		
INAKABA	Seedcorn beetle		
IOACAHA	Seedcorn maggot		

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Corn, Field cluster (continued)		
INAMBLA	Northern corn rootworm	1 lb/5-20 gal fluid fertilizer/A [40 inch row spacing] (4 lb/gal EC)	Use limited to Northcentral and Midwestern corn growing areas. Soil application at planting (band (split boot)). Apply subsurface split bands on each side of the corn row 1.25 to 1.5 inches to each side of the seed and 1 to 2 inches deep. Do not place in direct contact with the seed.
INAMBOA	Western corn rootworm		
IJDAABA	Garden symphylan	2 lb/A (5-20% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing. May be tank mixed with atrazine, 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl]amino]-2-methylpropionitrile, S-ethyl diisobutylthiocarbamate (Sutan +), S-ethyl dipropylthiocarbamate. Fluid fertilizers or water may be used as a carrier. Do not tank mix with S-ethyl dipropylthiocarbamate on sweet corn or popcorn.
INAMBLA	Northern corn rootworm	3-4 lb/A (4 lb/gal EC) or 4 lb/A (10-20% G)	
INAMBMA	Southern corn rootworm		
INAMBOA	Western corn rootworm		
ITBCALA	(Black cutworm)	4 lb/A (4 lb/gal EC)	
INAVAAA	Wireworms	4 lb/A (5-20% G) (4 lb/gal EC)	
INASDXA	Maize billbug	4 lb/A (10-20% G)	Use limited to Southeastern states. Preplant broadcast soil application. Incorporate into the soil by discing.
/15005AA	(Corn, Sweet)		
INAVAAA	Wireworms	2.2 oz/ 1,000 ft row [36 inch row spacing] (10-20% G)	Use limited to FL muck soils. Soil application at planting (band). Apply a 2 inch band over the furrow. Do not place in direct contact with the seed.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28012AA	Mint (Peppermint, Spearmint)		0.1 ppm mint (peppermint, spearmint, peppermint hay, and spearmint hay) Broadcast soil application (preplant or established plantings) through 2 pounds per acre. Do not apply terbacil for a minimum of 3 weeks before or after application. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
			Broadcast soil application to established plantings. Apply prior to spring growth.
/14011AA	Onion, Bulb		0.1 (root crop vegetables) In furrow soil application at planting through 0.6 ounce per 1,000 foot row with 20 inch row spacing. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IOACACA	Onion maggot	0.6 oz/ 1,000 ft row (5% G)	Soil application at planting (in seed furrow). May be used on all soil types.
		0.6 oz/ 1,000 ft row (10% G) (4 lb/gal EC)	Soil application at planting (in seed furrow). Use on organic soils only (soils containing 10 percent or more organic matter).

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28015AA	**Peanuts**		0.1 ppm (peanuts, peanut forage, peanut hay, peanut hulls) Banded soil application (after pegging) through 2 pounds per acre with 36 inch row spacing. Broadcast soil application (after pegging) through 4 pounds per acre. For soil applications after pegging, apply up to 30 days after pegging begins. All 20 percent granular formulations are RESTRICTED USE PESTICIDES.
ITBMBOA	Lesser cornstalk borer	2 lb/A [36 inch row spacing] (10-20% G)	Use limited to Southeastern states. Soil application after pegging (band). Apply an 18 inch band over rows at first sign of infestation.
		4 lb/A (10% G)	Use limited to Southeastern states. Broadcast soil application after pegging. May be applied by aircraft. Apply at first sign of infestation.
INAMBMA	Southern corn rootworm	2 lb/A [36 inch row spacing] (5-20% G)	Use limited to Southeastern states. Soil application at pegging (band). Apply an 18 inch band over rows.
IQAIADA	Burrower bug	1-2 lb/A [36 inch row spacing] (10% G)	Use limited to Southwestern states. Soil application after pegging (band). Apply 18 inch band over rows.
ITBMBOA ITAMBMA	Lesser cornstalk borer Southern corn rootworm	2 lb/A [36 inch row spacing] (10% G)	
ITBMBOA	Lesser cornstalk borer	1-1.4 lb/A [minimum 32 inch row spacing] (10% G)	Use limited to Southwestern states. Soil application after pegging (band). Apply 14 inch band over rows.
IQAIADA	Burrower bug	2 lb/A (10% G)	Use limited to TX. Broadcast soil application. Incorporate into the soil with 1 to 2 inches of water.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28017AA	**Peppers**		0.1 ppm (fruiting vegetables) Broadcast soil application (preplant) through 4 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
INAVAAA	Wireworms	4 lb/A (4 lb/gal EC)	
/14013AA	**Potato, Irish**		0.1 ppm (root crop vegetables) Broadcast soil application (preplant) through 4 pounds per acre. Banded soil application (at planting) through 2 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing. May be tank mixed with 2-ethyl dipropylthiocarbamate in Northern, Western, and Pacific Northwest regions.
INAVAAA	Wireworms	4 lb/A (5-10% G) (4 lb/gal EC)	
INAVAAA	Wireworms	2 lb/A [36 inch row spacing] (10% G)	Use limited to the Pacific Northwest states. Soil application at planting (band). Apply subsurface bands 3 to 4 inches from and 2 inches below the seed pieces.
		2 lb/A [36 inch row spacing] (4 lb/gal EC)	Use limited to Northwestern states. Soil application at planting (band). Apply in liquid fertilizer. Apply through fluid fertilizer shank immediately ahead of the planter. Set shank to run 8 to 10 inches deep.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Potato, Irish (continued)		
IJDAABA	Garden symphylan	0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
INAVAAA	Wireworms	0.16 oz/ 100 sq.ft (2% G)	
/24014AA	Radish		0.1 ppm (root crop vegetables) Broadcast soil application (preplant or at time of planting) through 2 pounds per acre.
IOACADA IJDAABA	Cabbage maggot Garden symphylan	2 lb/A (5-10% G)	Broadcast soil application prior to or at time of planting. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
/28019AA	Sorghum, Grain		0.1 ppm (sorghum, grain, fodder and forage) 14 day preharvest or pregrazing interval through 1 pound per acre. Do not make more than 2 applications per crop. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IRACDKA IRACDNA	Corn leaf aphid Greenbug	0.75 lb/A (10-15% G)	Use limited to TX. Foliar application to irrigated sorghum. Apply over the top by aircraft.
		0.75-1 lb/A [5-30 gal/A] (4 lb/gal EC)	Foliar application. Apply over the top. May be applied by aircraft.

EPA Index to Pesticide Chemicals

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01016AA	Strawberry		0.1 ppm Broadcast soil application (preplant) through 2 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.
/28020AA	Sugar Beets		0.1 ppm (sugar beet tops, root crop vegetables) Banded soil application (at planting time) through 1.5 pounds per acre. Broadcast soil application (preplant) through 4 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) and 20 percent granular formulations are RESTRICTED USE PESTICIDES.
IOAXACA	Sugarbeet root maggot	1-1.5 lb/A ⌊minimum 22 inch row spacing⌋ (10-20% G)	Use limited to CO and Northwest sugar beet growing areas. Soil application at planting (band). Apply 7 inch band over rows and incorporate lightly into the soil. Do not place in direct contact with the seed.
		1 oz/ 1,000 sq.ft (10% G)	Use limited to the Big Horn Basin of WY. Subsurface soil application at planting (band). Apply subsurface band 2 inches from seed furrow and 2 inches below the soil surface on the irrigated side of the row. Do not place in direct contact with the seed.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Sugar Beets (continued)		
1JDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
INAVAAA	Wireworms	4 lb/A (5-10% G) (4 lb/gal EC)	
/25003AA	Sugarcane		0.1 ppm Banded soil application (at time of planting) through 7.36 ounces per 1,000 foot row with 60 inch row spacing. Banded soil application (postemergent) through 10.88 ounces per 1,000 foot row with 60 inch row spacing. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) and 20 percent granular formulations are RESTRICTED USE PESTICIDES.
INBPAAA	White grubs	7.2-10.88 oz/ 1,000 ft row (15-20% G)	Use limited to Southwestern states. Postemergent soil application (band). Apply 20 inch band over top of the cane row. Lightly incorporate as close to the plants as possible. Irrigate after application. Apply at and up to 2 weeks following peak adult flight.
INAVAAA	Wireworms	5.44-7.36 oz/ 1,000 ft row (10% G) (4 lb/gal EC)	Soil application at planting (band). Apply 14 inch band over tops of seed pieces immediately ahead of covering discs. Apply high rate in areas outside of FL.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/14018AA	**Sweet Potato**		0.1 ppm (root crop vegetables) Broadcast soil application (at planting time or root swelling) through 4 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) and 20 percent granular formulations are RESTRICTED USE PESTICIDES.
INAMADC	Flea beetles (larvae) (including elongate flea beetle, pale-striped flea beetle, sweet-potato flea beetle, three-spotted flea beetle)	4 lb/A (4 lb/gal EC)	Broadcast soil application at planting. Incorporate into the soil by discing.
INAMADC	Flea beetles (larvae) (including elongate flea beetle, pale-striped flea beetle, sweet-potato flea beetle, three-spotted flea beetle)	4 lb/A (10-20% G)	Use limited to Southeastern states. Broadcast soil application at planting. Incorporate into the soil by discing.
		3 lb/A (10-20% G)	Use limited to Southeastern states. Broadcast soil application at root swelling. Apply over the top.
INAVAAA	Wireworms	4 lb/A (5-20% G)	Broadcast soil application at planting or root swelling. Apply at planting and incorporate into the soil by discing, or over the top at root swelling.
INAVAAA	Wireworms	2 lb/A (5% G)	Use limited to Southeastern states. Preplant broadcast soil application. Incorporate into the soil by discing.
		0.16 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/26003AA /26006AA	Tobacco		N.F. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
INAVAAA	Wireworms	1-2 lb/A (5-10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing. Apply prior to bedding and planting.
/26006AA	(Tobacco, Flue Cured)		
INAVAAA	Wireworms	1 lb/A (4 lb/gal EC)	Preplant broadcast soil application. Apply prior to bedding and planting. Tank mix with S-propyl butylethylthiocarbamate.
		1 lb/A (1 lb/gal EC)	Preplant broadcast soil application. Apply prior to bedding and planting. Formulated with S-propyl butylethylthiocarbamate.
/11005AA	Tomato		0.1 ppm (fruiting vegetables) Broadcast soil application (preplant) through 2 pounds per acre. Emulsifiable concentrates 44 percent and greater (4 pounds per gallon) are RESTRICTED USE PESTICIDES.
IJDAABA	Garden symphylan	2 lb/A (10% G) (4 lb/gal EC)	Preplant broadcast soil application. Incorporate into the soil by discing.
		0.08 oz/ 100 sq.ft (2% G)	Broadcast soil application prior to or at planting. Apply with a fertilizer spreader or by shaking from the canister. Incorporate with a rake or power tiller.

O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	ORNAMENTALS		
	(Lawns and Turf (including ground covers))		
015AA	Bahiagrass		
017AA	Bermudagrass		Do not water the lawn prior to treatment. Do not allow children and pets on lawns for 24 hours and until grass has completely dried. Gloves and shoes must be worn during handling and application.
019AA	Bluegrass		
050AA	St. Augustinegrass		
056AA	Zoysia Grass		
LAEA	Chinch bug	5.6-7.5 oz/ 5,000 sq.ft (2-5% G)	Application to established lawns and turf. Use the higher rate for heavy infestations. Apply with a lawn fertilizer spreader when pests first appear and repeat as needed. Water granules into the root zone for 10 to 15 minutes immediately after application. For chinch bugs in Southern states and for earwigs and sod webworms in the Southeast.
AAAA	Earwigs		
MABA	Sod webworms		
	AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS		
01500 AAAAA	Aerial Application		
	--	Refer to AGRICULTURAL CROPS	Corn (Field), Corn (Pop), Corn (Sweet), Peanuts, Sorghum (Grain)
900300 AAAAAA	Tank Mix		
	--	Refer to AGRICULTURAL CROPS	Beans (Dry), Beans (Green), Corn (Field), Corn (Pop), Corn (Sweet), Potato (Irish), Tobacco (Flue Cured)

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O-ETHYL S-PHENYL ETHYLPHOSPHONODITHIOATE

Listing of Registered Pesticide Products by Formulation

2% granular

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-02120

5% granular

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-01994   000476-02121

10% granular

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-01995

15% granular

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-02030

20% granular

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-02028

1 lb/gal emulsifiable concentrate

o-ethyl s-phenyl ethylphosphonodithioate (041701), S-propyl butylethylthiocarbamate (041403) plus xylene range aromatic solvent (086803)
000476-02071

4 lb/gal emulsifiable concentrate

o-ethyl s-phenyl ethylphosphonodithioate (041701)
000476-02190

o-ethyl s-phenyl ethylphosphonodithioate (041701) plus petroleum distillate (063503)
000476-02056   000476-02134

999999   State Label Registrations

CA Reg. No.
000476-04093

OR Reg. No.
000476-04094   000483-04590   000483-04591   000483-04593
001871-09820   001871-09821   035503-09485

TX Reg. No.
006735-04811

WA Reg. No.
007404-06537

WY Reg. No.
000476-04095

TABLE A

GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI (95 ± 2%)	Yes	00059851*	No
61-2 - Statement of Composition	TGAI	Partially	00059851*	Yes[3]
61-3 - Discussion of Formation of Unintentional Ingredients	TGAI	Partially	00059851*	Yes[4]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	00059851*	Yes[5]
62-2 - Certification of Limits	TGAI	No	00059851*	Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Yes	GS-0105-004	No
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00059851*	No
63-3 - Physical State	TGAI	Yes	00059851*	No
63-4 - Odor	TGAI	Yes	00059851*	No

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-5 - Melting Point	TGAI	Yes	00059851*	No
63-6 - Boiling Point	TGAI	Yes	00059851*	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00059851*	No
63- 8 - Solubility	TGAI OR PAI	Yes	00059851*	No
63- 9 - Vapor Pressure	PAI	Yes	00059851*	No
63-10 - Dissociation constant	PAI	Not Applicable		
63-11 - Octanol/water partition coefficient	PAI	Partially	00059851*	Yes[7]
63-12 - pH	TGAI	Yes	00059851*	No
63-13 - Stability	TGAI	Yes	00059851*	No
Other Requirements:				
64- 1 - Submittal of samples	Choice			

*Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than March 31, 1987.
3/ A statement is needed to indicate the procedure of the manufacturing process that is now in actual use.
4/ If the alternate procedure is in use, the possibility of introducing nitrosamine into the technical chemical should be discussed.
5/ A description of the method(s) and validating data used to obtain the preliminary analysis is needed. Five or more representative samples should be analyzed.
6/ Certification of limits is required for end-use products, also.
7/ Unless the registrant can relate the submitted solvent partition p-values to the octanol/water partition coefficient, data for the octanol/water partition coefficient will be needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	00052067* GS-0105-005 GS-0105-006 GS-0105-007 GS-0105-008 05018141	No[24]
- Livestock	PAIRA and plant metabolites	Partially	GS-0105-009 00090878* 00090875* 00090876* GS-0105-010 GS-0105-011	Yes[3][24]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	GS-0105-012 GS-0105-013 GS-0105-015 GS-0105-004	No[24]
- Animal residues	TGAI and metabolites	Yes	GS-0105-012 GS-0105-013 GS-0105-015 GS-0105-004	No[24]

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
171-4 - Storage Stability Data	PAI	Yes	GS-0105-013 GS-0105-015	No[24]/
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Root and Tuber Vegetables				
• Beets,Table (roots)	TEP	Yes	GS-0105-016	No
• Potatoes (Irish)	TEP	Partially	GS-0105-013 GS-0105-016	Yes[4]/[24]/
• Radishes (roots)	TEP	No		Yes[5]/
• Sugar Beets	TEP	No		Yes[5]/
• Sweet Potatoes	TEP	No		Yes[6]/
• Turnips (roots))	TEP	No		Yes[7]/
Leaves of Root and Tuber Vegetables				
• Beets, Table (leaves)	TEP	Yes	GS-0105-016	No
• Radishes (tops)	TEP	No		Yes[8]/
• Sugar Beets (tops)	TEP	No	GS-0105-016	Yes[5]/

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
Bulb Vegetables				
• Onions	TEP	Yes	GS-0105-016	No
Brassica (Cole) Leafy Vegetables				
• Broccoli	TEP	Yes	GS-0105-017*	No
• Brussels Sprouts	TEP	Yes	GS-0105-017*	No
• Cabbage	TEP	Yes	GS-0105-017*	No
• Cauliflower	TEP	Yes	GS-0105-017*	No
Legume Vegetables (Succulent or Dried)				
• Beans (green, dry, lima)	TEP	Yes	GS-0105-017*	No
• Soybeans	TEP	Yes	GS-0105-013	No
• Peas	TEP	No		No 9/

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
Foliage of Legume Vegetables				
• Bean Forage, Bean Vine Hay	TEP	Yes	GS-0105-016	No
• Pea Forage, Pea Vine Hay	TEP	No		Yes[10/]
• Soybean Forage and Hay	TEP	Yes	GS-0105-013	No
Fruiting Vegetables (except Curcurbits)				
• Peppers	TEP	Partially	GS-0105-014*	Yes[5/]
• Tomatoes	TEP	Yes	GS-0105-015	No
Small Fruits and Berries				
• Strawberries	TEP	Yes	GS-0105-017*	No

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
Cereal Grains				
• Corn (fresh corn and grain)	TEP	Partially	GS-0105-013	Yes[11]
• Sorghum (grain)	TEP	Partially	GS-0105-015	Yes[12]
Forage, Fodder, and Straw of Cereal Grains				
• Corn (fodder and forage)	TEP	Partially	GS-0105-013	Yes[13]
• Sorghum (fodder and forage)	TEP	Yes	GS-0105-015	No
Miscellaneous Crops				
• Asparagus	TEP	Partially	GS-0105-017*	Yes[14]
• Mint	TEP	Yes	GS-0105-017*	No
• Peanuts	TEP	Partially	GS-0105-013	Yes[15]
• Sugarcane	TEP	Partially	GS-0105-014*	Yes[16]
Residues in Tobacco	TEP	Partially	00090850	Yes[17]
Residues in Processed Commodities				
• Potatoes, Irish	TEP	No		Yes[18]

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry (continued)				
• Sugar Beets (roots)	TEP	Reserved[19]		
• Beans (green, dry, lima)	TEP	No		No[20]
• Soybeans	TEP	No		No[20]
• Tomatoes	TEP	No		No[20]
• Corn (fresh corn and grain)	TEP	Reserved[21]		
• Sorghum, grain	TEP	Reserved[22]		
• Mint	TEP	No		No[20]
• Peanuts	TEP	Reserved[22]		
• Sugarcane	TEP	Reserved[22]		
Magnitude of the Residue in Food Producing Animals				
• Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Reserved[23]		

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

§158.125 (Residue Chemisty
(continued)

1/ Composition: TGAI= Technical grade of the active ingredient; PAIRA= Pure active ingredient, radiolabelled; TEP= Typical end-use product; EP= End-use product.

2/ Data must be submitted no later than March 31, 1987.

3/ A lactating ruminant (cow or goat) metabolism study and a poultry metabolism study are required. Should the studies require a change in the existing nature of the tolerance to include other components, new analytical methods may also be necessary.

4/ The original residue data adequately supported the present tolerance. However, a petition for a higher tolerance is currently pending and awaits petitioner's response to data deficiencies.

5/ Data are required to reflect formulation types, maximum application rates, application methods, and geographical representation.

6/ The data do not support the tolerance, although no residues of fonofos and fonofos oxon could be detected from some aspects of this use. The over-the-top use is not represented by residue data.

7/ The data do not support the tolerance because of inadequate sampling. Additional data will be required if directions for use on turnips are established.

8/ There are no data for radishes, tops. Since there are directions for use on radishes, representative residue data must be submitted, or the conditions for the crop grouping "leaves of root and tuber vegetables" must be met.

9/ There are no residue data on peas, or peas-plus-pods. However, from the data on beans (green, dry, and lima), no residues of fonofos would be expected.

10/ The tolerance cannot be reassessed since there are no directions for use appearing on the label.

11/ The residue data, after elimination of unreliable values, do not support the tolerance for this major crop. Additional data on immature and mature corn reflecting the established use, including post-emergence (foliar) aerial applications and the major corn-growing areas, are needed. Residue data on the processed commodities of corn - oil (crude and refined), milled products, and cannery waste, are needed to determine if there is a concentration of residues.

12/ The number of studies is not adequate to support the use pattern with a short PHI (14 days). Residue data from representative growing areas reflecting this use must be submitted.

13/ Residue data on corn fodder and forage reflecting the registered uses, including the post-emergence (foliar) aerial application and the major corn-growing areas, are needed.

14/ Information is needed on how promptly samplings were analyzed.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

§158.125 Residue Chemistry
(continued)

15/ Additional data must be submitted reflecting established use patterns (including application by aircraft), at maximum application rates, and from major peanut-growing areas. Data on the processed commodities of peanuts - oil (crude and refined), meal, and soapstock are needed to determine if there is a concentration.

16/ Residue data, reflecting major geographical sites and a maximum number of possible postemergent applications to determine realistic residue levels, are needed.

17/ Residue data on freshly-harvested tobacco from representative growing areas are required. If residues at 0.1 ppm or more are detected, the pyrolysis products derived from the active ingredient must be characterized.

18/ A food/feed additive tolerance of 3 ppm will probably be necessary for processed potato waste. The data must constitute random samplings of processed potato waste from operations in the Pacific Northwest. Data is also required for potato granules, chips, and dried products from potatoes treated with fonofos.

19/ A decision on the need for a food additive tolerance is being withheld at this time. Residue data is required for processed commodities (dehydrated pulp, molasses, and refined sugar).

20/ Data not required because residues not found or expected in foods or processed commodities.

21/ A decision on the need for a food additive tolerance is being withheld at this time. If the required residue data for oil and milled products indicate a residue concentration exceeding the tolerance for the raw agricultural commodity, a food additive tolerance may be needed.

22/ A decision on the need for a food additive tolerance awaits submission of residue data on the raw agricultural commodity.

23/ No conclusions can be drawn about the carry-over of residues and the need for tolerances for residues in meat, milk, poultry and eggs until the requested metabolism (poultry and large lactating ruminant) studies, as well as the new feeding studies, have been submitted and evaluated.

24/ All data citations are required to support the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,H	No		Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No		Yes 4/
161-3 - On soil	TGAI or PAIRA	A	No		Yes 5/
161-4 - In Air	TGAI or PAIRA	A	No		Yes 6/
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,H	Yes	00073059** 00092024* 00052058*	No 7/18/
162-2 - Anaerobic Soil	TGAI or PAIRA	H	No		Yes 8/
162-3 - Anaerobic Aquatic	TGAI or PAIRA		Not Applicable		
162-4 - Aerobic Aquatic	TGAI or PAIRA		Not Applicable		
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,H	No		Yes 9/
163-2 - Volatility (Lab)	TEP	A	No		Yes 10/
163-3 - Volatility (Field)	TEP	A	No		Yes 11/

* Data submitted by Stauffer Chemical Co. These data may be compensable.

** Data submitted by Dow Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	Partially	00090827* 00041235* 00090871*	Yes 12/18/
164-2 - Aquatic (Sediment)	TEP		Not Applicable		
164-3 - Forestry	TEP		Not Applicable		
164-4 - Combination and Tank Mixes					Reserved 13/
164-5 - Soil, Long-term	TEP	A,H	No		No 14/
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes 15/
165-2 - Rotational Crops (Field)	TEP	A	No		Yes 16/
165-3 - Irrigated Crops	TEP		Not Applicable		
165-4 - In Fish	TGAI or PAIRA	A,B	Partially	GS-0105-018*	Yes 17/
165-5 - In Aquatic Non-Target Organisms	TEP		Not Applicable		

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than March 31, 1987 .

4/ The study submitted was done on tap water, not sterile, as required.

5/ Radioactivity was not determined in the aqueous phase of the soil/water suspension.

6/ No study submitted, but is required.

7/ The studies combined togeather will fulfill this data requirement.

8/ No study submitted, but is required.

9/ A TEP was used instead of the TGAI or PAIRA; bioassay not acceptable; inadequate control, column 7 inches; and 11.5" water used; an adsorption study is required for domestic use.

10/ Study submitted was not a TEP.

11/ No data submitted, but is required.

12/ Additional data required for representative granular formulation at a site in the corn belt.

13/ Data requirement for tank-mixes is reserved.

14/ Requirement depends upon results of aerobic soil metabolism studies; additional data are not required because more than one-half of application dissipated before the recommended second application.

15/ Study invalid because residues in the treated soil were extracted before the crops were planted.

16/ No data submitted, but all required.Depends upon finding significant residues from the confined study; decision to be made following submission and evaluation of the confined study results.

17/ An additional study is needed to provide residue data in visceral tissue and whole fish and to identify degradates.

18/ All data citations are required to support the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,H	Yes	00090807 00059863* 00090806 00078777* 00090833* 00059860* 00078777*	No 7/
81-2 - Dermal LD_{50} - Rabbit	TGAI	A,B,H	Yes	00059860* 00059863* 00090807 00090836* 00090806 00078777*	No 7/
81-3 - Inhalation LC_{50} Rat	TGAI	A,B,H	Yes	00059859* 00059862*	No 7/
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,H	Partially	00090817 00090819	Yes 9/

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,H	Yes	00090807 00059863* 00090806 00078777* 00090833* 00059860* 00078777*	No 7/
81-2 - Dermal LD_{50} - Rabbit	TGAI	A,B,H	Yes	00059860* 00059863* 00090807 00090836* 00090806 00078777*	No 7/
81-3 - Inhalation LC_{50} Rat	TGAI	A,B,H	Yes	00059859* 00059862*	No 7/
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,H	Partially	00090817 00090819	Yes 9/

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B,H	Partially	00090818	Yes 4/
82-2 - 21-Day Dermal - Rabbit	TGAI	NA			
82-3 - 90-Day Dermal - Rabbit	TGAI	NA			
82-4 - 90-Day Inhalation - Rat	TGAI	NA			
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A,B,H			Provisional 5/
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,H	Partially	00082233* 00082232*	Yes (rodent) 8/
83-2 - Oncogenicity - 2 species: Rat and Mouse preferred	TGAI	A,B,H	Partially	00082232*	Yes (2 rodents)
83-3 - Teratogenicity - 2 species	TGAI	A,B,H	Partially	00118423*	Yes (1 rodent)
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,H	Yes	00082234*	No

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B,H	No		Yes 4/
132-1 - Soil Dissipation	TEP	A,B,H	No		Yes 4/
133-3 - Dermal Exposure	TEP	A,B,H	No		Yes 4/
133-4 - Inhalation Exposure	TEP	A,B,H	No		Yes 4/

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than March 31, 1987 .

4/ For each crop including home lawn and home garden, the registrant is required to propose an acceptable reentry interval based on one of the following: (a) data on dissipation of foliar and/or soil residues of fonofos (decline curve), on human exposure to those residues, and on toxicity of fonofos; or (b) determination of that time beyond which there are no detectable, dislogeable residues remaining in the worker environment.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	Yes	00090861* 00092027	No[5]
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	00022923	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,H	Not Required		
71-4 - Avian Reproduction	TGAI	A,B,H	Not Required		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,H	Yes	00090849* 00090882* 00090862* GS-0105-001* GS-0105-002*	No[6]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,H	Yes	00052064* 00090820 GS-0105-003	No[7]
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	No		Yes
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI		Not Required		
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,H	No		Yes

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI	A,B,H	Reserved4/		
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A,B,H	Not Required		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B,H	Reserved4/		

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than March 31, 1987.

4/ Reserved pending results of 72-4 and outstanding environmental fate data.

5/ Data citation 00090861 stands alone to fulfill the data requirement; 00092027 is considered useful information and may be used in conjunction with other data to fulfill the requirement.

6/Data citations GS-0105-001 and GS-0105-002 stand alone to fulfill the data requirement; the other citations are considered useful information and may be used in conjunction with other data to fulfill requirements.

7/ Data citations GS-0105-003, 00052064 and 00090820 each stand alone to fulfill the data requirement for a warmwater species; GS-0105-003 and 00090820 each stand alone to fulfill the coldwater species data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No	-	No 3/
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 3/
122-1 - Vegetative Vigor	TGAI		No	-	No 3/
122-2 - Aquatic Plant Growth	TGAI		No	-	No 3/
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 3/
123-1 - Vegetative Vigor	TGAI		No	-	No 3/
123-2 - Aquatic Plant Growth	TGAI		No	-	No 3/
TIER III					
124-1 - Terrestrial Field	TEP		No	-	No 3/
124-2 - Aquatic Field	TEP		No	-	No 3/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ These requirements are generally waived unless it is believed there is a phototoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B,H	Yes	00043714**** 05001991	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,H	Yes	00056152*****	No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A,B,H	Not Applicable		
141-4 - Honey bee subacute feeding study	(Reserved)				
141-5 - Field testing for pollinators	TEP	A,B,H	Not Applicable		

**** Data submitted by ICI Americas, Inc. These data may be compensable.
***** Data submitted by Thompson-Hayward Chemical Co. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FONOFOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)				
142-2 - Aquatic insect life-cycle study	(Reserved)				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than March 31, 1987.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FONOFOS

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2,8]
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Yes	00059851*	No
61-2 - Statement of Composition	MP	Partially	00059851*	Yes[3]
61-3 - Discussion of Formation of Unintentional Ingredients	MP	Partially	00059851*	Yes[4]
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partially	00059851*	Yes[5]
62-2 - Certification of Limits	MP	No		Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	MP	Yes	GS-0105-004	No
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00059851*	No
63-3 - Physical State	MP	Yes	00059851*	No
63-4 - Odor	MP	Yes	00059851*	No
63-7 - Density, bulk density, or specific gravity	MP	Yes	00059851*	No

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FONOFOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	Yes	00059851*	No
63-14 - Oxidizing or reducing action	MP	No		Yes
63-15 - Flammability	MP	Partially	00059851	Yes 7/
63-16 - Explodability	MP	No		Yes
63-17 - Storage Stability	MP	No		Yes
63-18 - Viscosity	MP	No		Yes
63-19 - Miscibility	MP	Not Applicable		
63-20 - Corrosion Characteristics	MP	No		Yes
Other Requirements				
64- 1 - Submittal of Samples	Not Required			

* Data submitted by Stauffer Chemical Co. Data may be compensable.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FONOFOS

§158.120 Product Chemistry
(continued)

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than September 30, 1984.

3/ A statement is needed to indicate the procedure of the manufacturing process that is now in actual use.

4/ If the alternate procedure is in use, the registrant should discuss the possibility of introducing nitrosamine into the technical chemical.

5/ A description of the method(s) and validating data used to obtain the preliminary analysis is needed. Five or more representative samples should be analyzed.

6/ Certification of limits is required.

7/ The registrant should confirm that the submitted flash point is indeed the flashpoint for the technical chemical.

8/ Data reviewed refer only to Stauffer's technical grade material. There is no manufacturing-use product registered.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FONOFOS

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2][3]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00090807 00059863* 00090806 00078777* 00090833* 00059860*	No[4]
81-2 - Dermal LD_{50} - Rabbit	MP	Yes	00059860* 00059863* 00090807 00090836* 00090806 00078777*	No[4]
81-3 - Inhalation LC_{50} - Rat	MP	Yes	00059859* 00059862*	No[4]
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00078777*	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00059856* 00078777*	No[4]
81-6 - Dermal Sensitization - Guinea Pig	MP	No		Yes

* Data submitted by Stauffer Chemical Co. These data may be compensable.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FONOFOS

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than September 30, 1984.
3/ Data reviewed refer only to Stauffer's technical grade material. There is no manufacturing-use product registered.
4/ Each of these data citations stand alone to fulfill the data requirement.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines [2], or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This Section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to end-use products only to the the extent described under Section II of this document. Otherwise, the following information pertains exclusively to manufacturing-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 an IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this Section and/or Section II, EPA may issue a notice of intent to cancel the registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C) determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix IV-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Product Manager William H. Miller
Phone No. (703) 557-2600
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant may submit such labeling. (End-use product labeling needs to comply specifically with the instruction in Section II of this guidance document.) The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for stortage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

After the Supreme Court has ruled on the Monsanto Decision, you will be informed as to when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the associated data support information.

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Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________ Guidance Document for ____________________________

Date ____________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

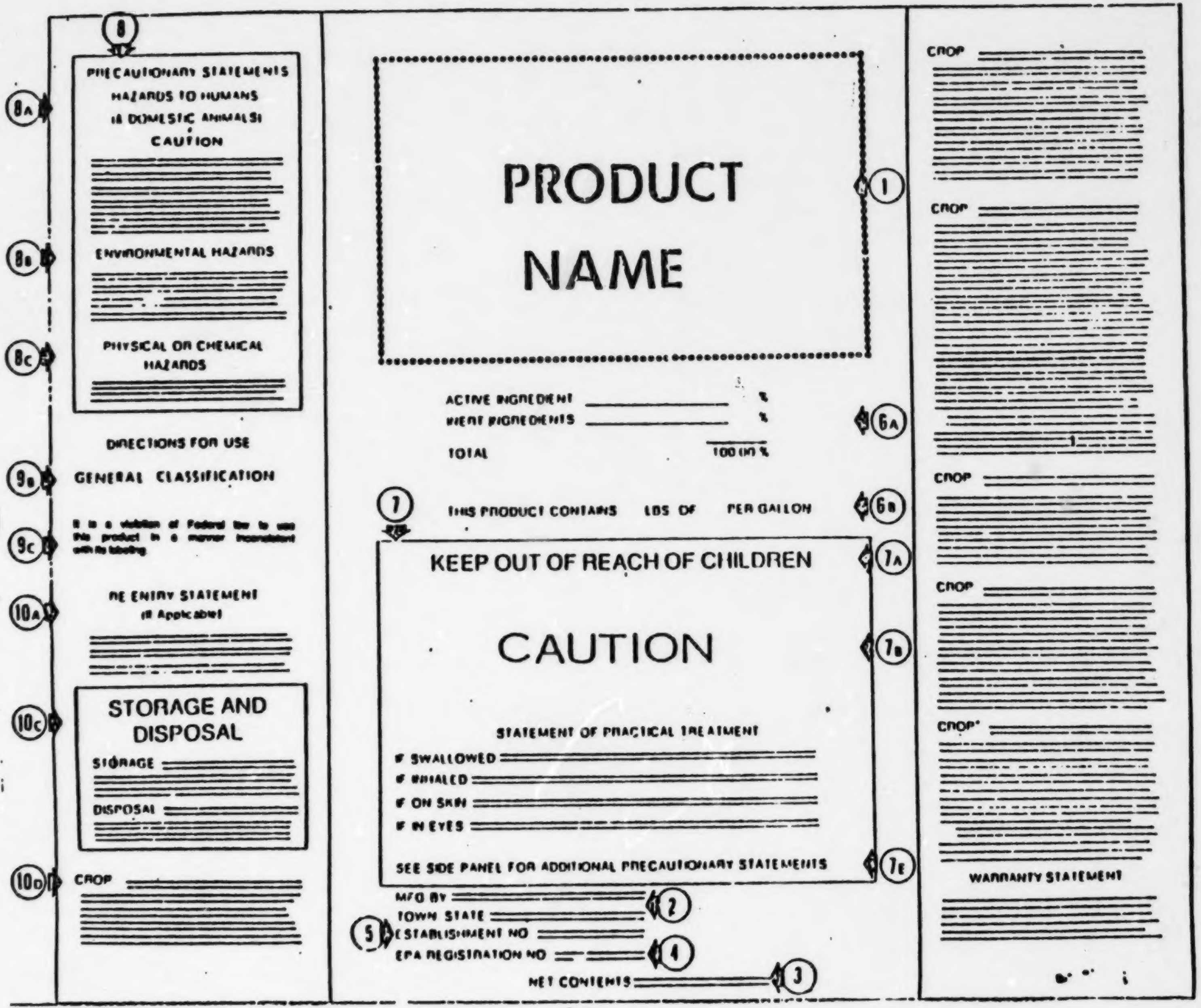
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

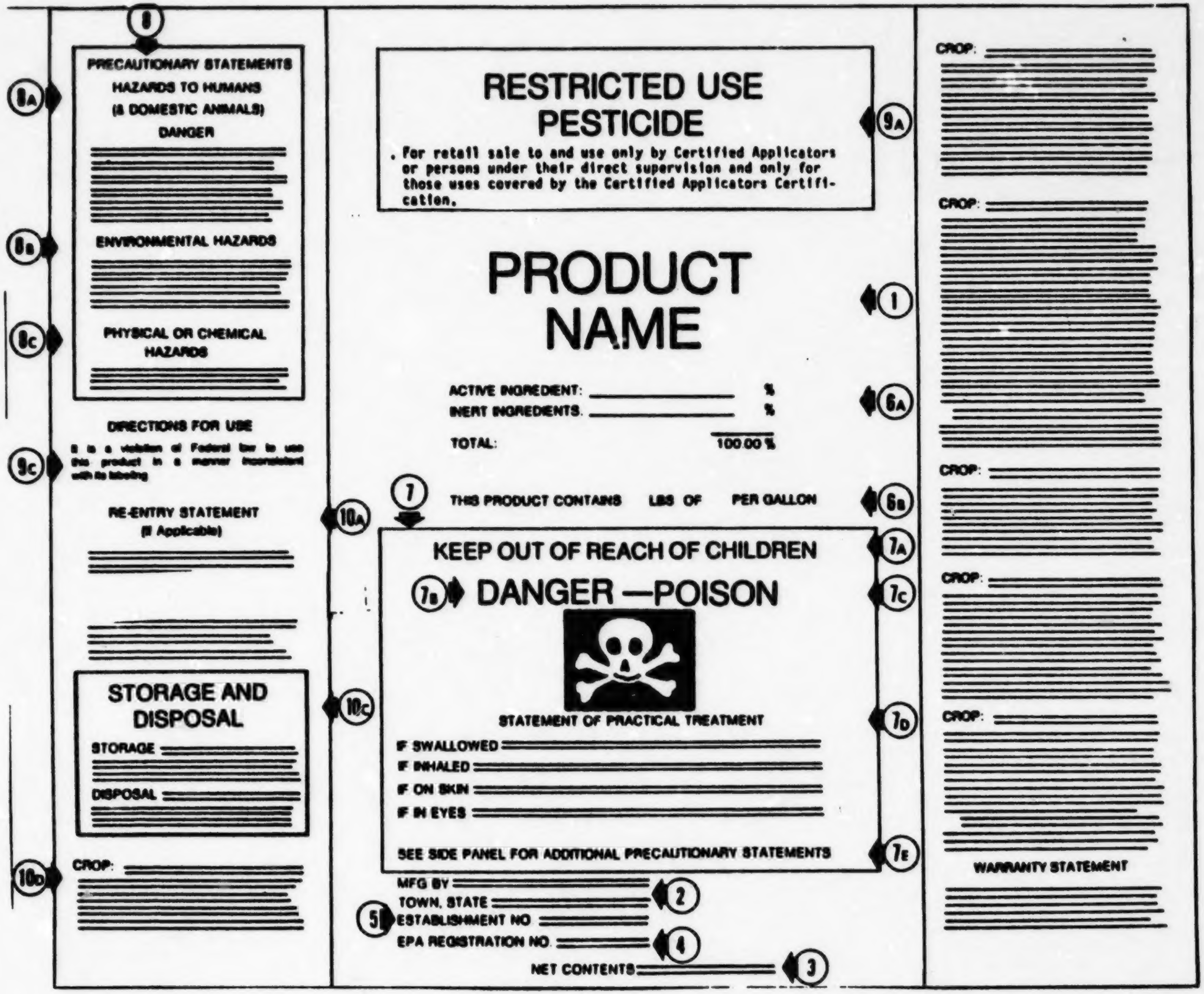
APPENDIX IV-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.


8
8A
8B
8C
9B
9C
10A
10C
10D
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
GENERAL CLASSIFICATION
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
RE ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
PRODUCT NAME
1
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL 100.00 %
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT


8
8A
8B
8C
9C
10A
10C
10D
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
RE-ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP:
RESTRICTED USE PESTICIDE
9A
PRODUCT NAME
1
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
6A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
7
KEEP OUT OF REACH OF CHILDREN
7A
7B
DANGER —POISON
7C
STATEMENT OF PRACTICAL TREATMENT
7D
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO.
4
NET CONTENTS
3
CROP:
CROP:
CROP:
CROP:
CROP:
WARRANTY STATEMENT

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.

Appendix II-2

OMB Approval No. 2000-0468 (Expires 12

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSU

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

Appendix II-3

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________Guidance Document for____________________________

Date____________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Appendix III-1 (continued)

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX IV-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Appendix IV-5
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-5
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Fonofos as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.
2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.
3. Sets out time-frames for submission of required data.
4. Explains how to revise labeling for manufacturing use products.
5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

William H. Miller
Product Manager 16
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone 703/557-2600

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).